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10/532,772	04/21/2005	Philip Bickford Smith	15975US	6668

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EXAMINER

ANDERSON, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

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11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,772

Applicant(s)

BICKFORD SMITH ET AL.

Examiner

Michael J. Anderson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16, 18-27, 29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Segal (US patent # 6,402,207) (Segal).

With regard to claim 1 Segal discloses, a system of medical small bore tubing for multiple different applications (figures 1-7), the system in each application comprising connectors (element # 1) between tubing (36, 505) of the system or components of the system (figures 1-7), wherein said connectors comprise: a male component (1) having a stub (15), a first key (29) and a through-bore (4) for the passage of fluid to be transported; and a female (3) component having a stub (30), a second key (35) and a through-bore (4) for the passage of fluid to be transported; said male and female components being adapted to be interconnected in a fluid-tight manner with inter-engagement of said first and second keys, and said stubs being adapted for connection to tubing of the system or components of the system (figure 2), and at least one of said male and female components having a grip (32); wherein, in each application: a) the first and second keys are unique to each application of the system so that they prevent connection of a female component of one application to a male component of another application (figures 2-7); and b) said grip has application affordance unique to the application for which it is intended (figure 5), the affordance comprising both visual and

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tactile cues (figure 5); wherein misconnections between tubing and components of said different applications of the system are prevented and attempts by users to effect said misconnection are discouraged by said affordance of said grip (column 2, lines 12-19 and column 5, lines 31-46; figures 5 and 7).

With regard to claim 2, Segal discloses as for claim 1 and further discloses, wherein said application affordance comprises a shape of the grip that is suggestive of a part of a human body for which the application is intended (column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; figures 5 and 7).

With regard to claim 3, Segal discloses as for claim 2 and further discloses, wherein a first application is neuraxial, and said shape of the grip is generally cylindrical having a longitudinal spine and encircling ribs suggestive of the human spine and ribs (figure 7A, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46; figures 5 and 7).

With regard to claim 4, Segal discloses as for claim 2 and further discloses, wherein a second application is respiratory, and said shape of the grip is generally cylindrical having alternating frusto-conical sections suggestive of a bellows (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 5, Segal discloses as for claim 2 and further discloses, wherein a third application is enteral, and said shape of the grip is generally cylindrical with bulges down its length suggestive of the human colon (figures 5 and 7; column 6,

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lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 6, Segal discloses as for claim 2 and further discloses, wherein said visual and tactile cues of the application affordance are provided only by said shape of the grip (figures 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 7, Segal discloses as for claim 1 and further discloses wherein said grip also comprises a mechanism affordance unique to a method of interconnection between said male and female components (figures 2, 3, 5 and 7; column 6, lines 37-64, and column 8, lines 33-49 and column 2, lines 12-19 and column 5, lines 31-46).

With regard to claim 8, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a twisting step (figure 1 locking system must be twisted); and wherein said mechanism affordance comprises a wing of said grip (column 7, lines 57-67 and figure 2, elements 29 and 35).

With regard to claim 9, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a pushing step (figure 1 locking system must be pushed); and wherein said mechanism affordance comprises a waist of said grip (column 7, lines 57-67 and figure 2, elements 29 and 35).

With regard to claim 10, Segal discloses as for claim 7 and further discloses, wherein said method of interconnection comprises a locking step (figure 1 locking

system); and wherein said mechanism affordance comprises a button of said grip (column 7, lines 57-67 and figure 2, elements 29 and 35 and figure 6).

With regard to claim 11, Segal discloses as for claim 1 and further discloses the kit comprising: a first converter having: a through bore; a standard female connector; a different male connector element; and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6); and a second converter having: a through bore; a standard male connectors; a different female connector that corresponds with the different male connector of said first converter (figures 4 and 6); and a flange adapted for engagement with the latching mechanism of said first converter (figures 4 and 6).

With regard to claim 12, Segal discloses as for claim 11 and further discloses in which said standard connectors are 6% luer connectors (figure 2, elements 50 and 55).

With regard to claim 13, Segal discloses as for claim 11 and further discloses in which said different connectors are reduced-diameter 6% conical connectors (figure 4).

With regard to claim 14, Segal discloses as for claim 13 and further discloses in which said reduced-diameter comprises about 3 mm for the end of the male connector, and about 3.3 mm for the opening of the female connector, and wherein each connector has a length of about 7.5 mm (figure 4).

With regard to claim 15, Segal discloses as for claim 11 and further discloses a syringe (figure 7, 545), the syringe having a standard outlet (figure 7); wherein the standard outlet is permanently secured to the first converter (figure 7).

With regard to claim 16, Segal discloses as for claim 15 and further discloses wherein the standard outlet is permanently secured to the first converter by welding or adhering said first converter to said outlet (columns 7-8).

With regard to claim 18, Segal discloses as for claim 11 and further discloses a hypodermic needle (545), said needle having said different female connector formed directly thereon (figures 4 and 7 column 8, lines 50-67).

With regard to claim 19, Segal discloses as for claim 11 and further discloses, wherein said latching mechanism comprises a threaded collar and said flange comprises thread elements (column 9, lines 17-65).

With regard to claim 20, Segal discloses as for claim 19 and further discloses wherein the latching mechanism on the first converter is axially slidable between limits, and is rotatably free (figures 2, 4 and 6).

With regard to claim 21, Segal discloses as for claim 11 and further discloses, wherein the latching mechanism is visually coded to identify a class of medical applications for which it is intended (figures 5 and 7; column 6, lines 1-64, and column 8, lines 33-49).

With regard to claim 22, Segal discloses as for claim 11 and further discloses, wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with flange elements provided on the standard female connector of said first converter to lock said standard male and female connectors together (figures 2, 4 and 6).

With regard to claim 23, Segal discloses as for claim 11 and further discloses, wherein said different female connector comprises a face having castellations; and wherein leak paths are provided between said castellations in the event that a standard male connector is butted against said face (columns 6-8).

With regard to claim 24, Segal discloses as for claim 11 and further discloses, the syringe comprising an outlet having a different male connector to a standard male connector and a latching mechanism on the different male connector adapted to engage a flange of a corresponding female connector to which said different male connector is sealingly mateable (figures 4 and 6).

With regard to claim 25, Segal discloses as for claim 11 and further discloses, component of medical tubing having a standard male connector and a standard female connector to which a first connector and a second connector of a kit as claimed in claim 11 have been connected (figures 1-7).

With regard to claim 26, Segal discloses as for claim 25 and further discloses, wherein the standard female connector of said first converter comprises flange elements; and wherein the standard male connector of said second converter has an integral latching mechanism formed thereon adapted to co-operate with the flange elements on of the standard female connector of said first converter to lock said standard male and female connectors together, and wherein said connections have been rendered permanent by application of adhesive between a latching mechanism on the component and the standard female connector of the first converter and between

the latching mechanism of the second converter and the female connector of the component (columns 7-8).

With regard to claim 27, Segal discloses as for claim 25 and further discloses, which component is a filter, valve or tube junction (figure 7).

With regard to claim 31, Segal discloses as for claim 1 and further discloses, the article comprising: a connector having a male or female component, a stub, a grip, a key and a through-bore for the passage of fluid to be transported, said component being adapted to be connected in a fluid-tight manner with a corresponding component of another connector and with inter-engagement of said key with the key of said other component, and said stub being connected to said article; wherein said grip has application affordance unique to the application for which the article is intended, the affordance comprising both visual and tactile cues (column 2, lines 12-19 and column 5, lines 31-46).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 17, 28-30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Segal in view of Moberg (US patent # 6,659,980) (Moberg). Segal teaches as for

claims 11 and 16. Segal does not teach permanent ultrasonic welding or adhesion. Moberg teaches ultrasonic welding and adhesion.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify Segal as taught by Moberg for the purpose of creating a permanent connection. One skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

Response to Amendment

The present communication responds to the Amendment of 09/06/2007. By this communication, no claims were amended. Claims 1-31 are pending. The rejection(s) are as stated.

Response to Arguments

Applicant's arguments filed 9/6/2007 have been fully considered but they are not persuasive. That claims 1-7 contain an application affordance which can comprise, for example, a shape suggestive of a human spine and rib cage for neuraxial uses; a bellows-like shape suggestive of air flow for respiratory applications; and a bulbous shape suggestive of a human colon for enteral applications is not persuasive for reasons addressed because, Segal discloses (column 2, lines 12-19 and column 5, lines 31-46) the use of paired connectors, each coded for use with only one type of medical catheter or device and that the connectors are designed to be application or path specific.

With regards to applicants argument concerning claim 1 that Segal does not disclose "said grip has application affordance unique to the application for which it is intended, the affordance comprising both visual and tactile cues." Applicant acknowledges that Segal et al. discloses a connection system having converters with standard luer connections, and different interconnections. A key is provided in the form of surface features that prevent incorrect connections. The surface features may be geometric shapes, such as triangles, squares, pentagons, hexagons, or other regular polygon or quadrilateral shape. See, col. 6, lines 43 to 47. "The identity of the connector type is readily recognizable by the skilled artisan from the shape or design of the mating surfaces, as well as from the distinctive markings on the outer surfaces of the half connectors. These markings can include texture features, color-coding and/or text labels, such as labels 70." See, col. 5, lines 41-45. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., affordance) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

With regards to applicants argument concerning claims 8-10 that Segal does not disclose "wherein said method of interconnection comprises a twisting step; and wherein said mechanism affordance comprises a wing of said grip", "wherein said method of interconnection comprises a pushing step; and wherein said mechanism affordance comprises a waist of said grip" and "wherein said method of interconnection

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comprises a locking step; and wherein said mechanism affordance comprises a button of said grip." Segal discloses (column 7, lines 57-67, figures 2 and 6, elements 29, 32, 35, 44 70 and 405) wings, a waist and a button.

The 35 U.S.C. 102(b) rejections of claims 17, 28 and 30 are **withdrawn**.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael J. Anderson whose telephone number is (571) 272-2764. The examiner can normally be reached on M-F 6:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Simons can be reached on (571) 272-4965. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael J Anderson
Examiner
Art Unit 3767

MJA
11/16/2007

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Handwritten signature of Kevin C. Sirmons in black ink.